

Application Number 10/696,781
Responsive to Office Action mailed September 22, 2006

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REMARKS

This communication is responsive to the Final Office Action dated September 22, 2006.
Claims 1-65 are pending.

Allowable Subject Matter

The Final Office Action indicated that claims 9, 13, 14, 31, 36, 40, 55, 59 and 60 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant appreciates this indication of allowability for claims 9, 13, 14, 31, 36, 40, 55, 59, and 60.

However, for at least the reasons given below, Applicant respectfully suggests that independent claims 1, 17, and 47 are in condition for allowance. Therefore, at this time, Applicants do not amend dependent claims 9, 13, 14, 31, 36, 40, 55, 59, and 60 to place them into independent form.

Claim Rejection Under 35 U.S.C. § 103

The Final Office Action maintained the rejection of claims 1-8, 10-12, 15-30, 32-35, 37-39, 41-54, 56-58 and 61-65 under 35 U.S.C. § 103(a) as being unpatentable over Mann (US 6,052,624). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Independent claims 1, 17, and 47

In the previous Amendment, Applicant argued at length that Mann fails to disclose or suggest calibrating a map that maps an output of a control device to values of at least one electrical stimulation parameter based on information received from a user of the control device that reflects paresthesia experienced by a patient, as required by independent claim 1, or the similar requirements of independent claims 17 and 47.

Mann teaches an electrode group location/size map generator circuit 50 and selection software algorithms that determine an electrode configuration based on directional input from a

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joystick.¹ However, Mann does not disclose or suggest that the software algorithms are calibrated (or even modified in any fashion), much less that the software algorithms are calibrated based on information received from a user of the control device that reflects paresthesia experienced by a patient. Instead, they are fixed, and used in their fixed form to determine electrode configurations based on directional input.

Furthermore, the Office Actions have cited no other evidence of any teaching in the prior art that would have suggested modification of Mann to include calibration of the software algorithms to a person of ordinary skill in the art. In fact, the Office Actions have cited no evidence of prior art teachings other than Mann. For at least this reason, the Office Actions have failed to establish a prima facie case of unpatentability of Applicant's claims under section 103.

In support of the rejection, the Final Office Action cited text within Mann, which purportedly supports the conclusion that Mann teaches use of feedback from the patient to determine stimulation parameters, which can then be stored in memory for later use. However, this is merely a teaching relating to use of a joystick and apparently fixed, uncalibrated software algorithms to adjust stimulation based on patient feedback.² Mann does not teach that the algorithms are modified based on the feedback. Instead, the joystick is moved based on patient feedback, and the electrode combination is determined based on joystick movement according to the uncalibrated algorithms. Thus, this teaching is irrelevant to the calibration requirements of Applicant's claims, and does not support the maintenance of the rejections based on Mann in the Final Office Action.

As described in Applicant's specification, a map may, for example, map output from a control device to electrode combinations. A patient experiences paresthesia based the location of electrodes that deliver the stimulation and strength of the stimulation pulses. Consequently, manipulating the control device may correspond to selecting a group of electrodes that deliver therapy resulting in paresthesia experienced by the patient in the direction of movement.

Calibrating the map, however, requires changing the initial mapping between the output of the control device and the therapy parameters. Calibration may, for example, change the mapping such that different electrodes or other stimulation parameters are selected, relative to an

¹ Mann, col. 9, ll. 42-45 and col. 12, ll. 41-46.

² Mann, col. 14, ll. 25-33.

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uncalibrated map, in response to the same manipulation of the control device. According to lines 9-11 of paragraph [0057] in Applicants' specification, "The calibration may include altering electrode combinations of the selected fixed map 62 to match the direction of movement of paresthesia for patient 34 to the direction of movement of a direction controller 20 of control device 12."

In some cases, calibrating the map provides distinct advantages. For example, it is conceivable that a patient may experience paresthesia substantially differently than a "normal" patient because of differences in anatomy and/or physiology. Manipulating the control device using the initial mapping may, as a result, not provide an intuitive manner for controlling the location of paresthesia experienced by the patient. However, calibrating the map according to the patient's experience of paresthesia, for example during a test session, according to the patient's experience of paresthesia, may allow the patient to control the location of paresthesia by intuitively manipulating the control device.

Mann teaches use of an algorithm to determine electrode configurations based on input from a joystick. Mann fails to teach or suggest calibrating the algorithm. For at least this reason, Mann fails to teach or suggest calibrating a map that maps an output of a control device to values of at least one electrical stimulation parameter of a stimulation device, as required by Applicants' independent claims 1, 17, and 47.

Dependent claims

In a similar manner, Mann fails to teach or suggest the features of dependent claims 2-8, 10-12, 15, 16, 18-30, 32-35, 37-39, 41-46, 48-54, 56-58, 61 and 62. For example, claims 4, 25 and 50 recite that calibrating a map comprises receiving outputs from the control device that reflect manipulation of the directional controller to a plurality of predetermined locations, receiving information that reflects paresthesia experienced by the patient when the directional controller is located at each of the locations, and adapting a fixed map based on the outputs and the paresthesia information. Mann does not describe receiving *any* patient feedback information from the user of the control device for calibration of the map. These limitations have not been addressed in either of the Office Actions. No portion of Mann has even been identified in the Office Actions as allegedly teaching these limitations of claims 4, 25 and 50.

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In fact, most of the limitations in Applicant's numerous dependent claims have similarly never been addressed in either of the Office Actions, and yet these dependent claims are now finally rejected. The Office Actions have included only few citations to passages within Mann, with no indications as to which claims or limitations these passages apply, nor any explanation of their applicability to Applicants claims. Because they are inadequate in this regard, the Office Actions have provided Applicant with no guidance as to how to advance prosecution of the application.

Moreover, for this reason, the Office Actions do not comply with the requirements of 37 C.F.R. § 1.104(c)(2). Applicant respectfully requests that any Advisory Action or other subsequent Action the include a discussion of each of Applicant's claims, including, for each claim, an identification of what portion of any cited reference applies to the claim, and an explanation of the relevance of the cited portion to the claim, in accordance with the requirements of 37 C.F.R. § 1.104.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicants' claims 1-8, 10-12, 15-30, 32-35, 37-39, 41-54, 56-58, 61 and 62 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

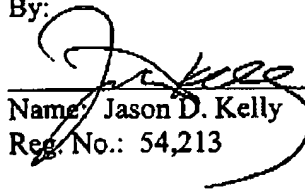
CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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11/22/06
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